July 13, 1999

DOCKETS MANAGEMENT BRANCH (HFA-305) FOOD AND DRUG ADMINISTRATION 5630 FISHERS LANE ROOM 1061 ROCKVILLE, MD 20857-1265

RE: DOCKET NO. 98N-1265

To the FDA:

As a consumer and a user of compounded medication, I would strongly register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act restricts my rights as a patient to obtain the product I have been using for 5 years. I have tried to obtain my compounded prescription from Walgreen's but the large drug chains do not compound, so where is a consumer supposed to go. When you find a prescription that works for you, after trying other forms of hormone therapy, why not continue.

It sounds like the HMO's are making a strong case for doing away with compounded medications. I know for a fact because my HMO did not want to continue paying for the compounded medication that I am now receiving. It sounds like the HMO's have even the FDA over the barrel to comply with their wishes to do away with compounded medication.

The consumer/patients have no recourse when it comes to big money.

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. This is not a Safety Issue! As a government agency, the FDA has a responsibility to be accountable to the people, not just the HMO's. Please amend the MOU.

Mrs. Evelyn Lucas

State of Residence: Illinois

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E. Lucas Glenview, IL 60025





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